DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 14, 2015

S & C Polymer Silicon- und Composite Spezialitaeten GmbH
Dr. Christian Boettcher
Official Corresponent / Director Regulatory Affairs
Robert-Bosch-Strasse 2
Elmshorn, Schleswig-Holstein 25335
GERMANY

Re: K141047
Trade/Device Name: LC Calcium Hydroxide Liner
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: March 5, 2015
Received: March 9, 2015

Dear Dr. Boettcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141047

Device Name
LC Calcium Hydroxide Liner

Indications for Use *(Describe)*
Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping)

Lining of cavities for following filling procedures

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter

Name of company: S&C Polymer Silicon- und Composite Spezialitaeten GmbH
Address: Robert-Bosch-Strasse 2, D-25335 Elmshorn (Germany)
Phone: 0049 4121 483 0
Fax: 0049 4121 483 184
Contact Person: Dr. Christian Boettcher

Date of preparation: April 6th 2015

Device Name:

Trade name:	LC Calcium Hydroxide Liner
Common Name:	Calcium Hydroxide Liner
Classification Name:	Liner, Cavity, Calcium Hydroxide, per 21CFR § 872.3250
Classification:	II
Product Code:	EJK

Devices for which Substantial Equivalence is Claimed:

Calcimol LC, VOCO GmbH, K 924182

Device description:

LC Calcium Hydroxide Liner is a radiopaque one component visible light curing liner containing calcium hydroxide. It is intended for indirect pulp capping and for lining of cavities where filling procedures will follow and can be applied in thin layers followed by light curing of the material. The chemical components include fillers, resins, an alkalining agent, as well an initiator.

Intended Use of the Devices:

LC Calcium Hydroxide Liner is intended for:

- Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping)
- lining of cavities for following filling procedures

Performance Data:

Non-clinical performance data for this device included the following:

Working time, the barcol hardness and the pH-value.

Testing also included water sorption, water solubility, and flexural strength , and depth of cure were all tested according to ISO 4049.

Technological Characteristics:

	Subject device	Predicate device
Appearance	white paste	white paste
Form of delivery	black syringe	black syringe
Method of polymerization	light cure	light cure
Application	extrusion via pressure onto the back of the syringe followed by application through needles	extrusion via pressure onto the back of the syringe followed by application through needles
Ingredients (general description)	fillers resins alkalining agent initiators	fillers resins alkalining agent initiators
Mechanism of Action	application light curing	application light curing

The subject device shares both similarities and differences to the noted predicate. The subject device has the same chemical composition as the predicate device; however, the subject device has been reformulated using different quantities of the chemical components. Performance testing was done to validate the change in the chemical composition and the subject device was found to perform as well as the predicate.

In regards to the intended use, the Indication for Use, the target population, the anatomical sites, the design, the performance, the standards to be met, the materials, and the biocompatibility the product of this submission is substantially equivalent to the predicate device.